

Massachusetts Department of Public Health

Division of Health Care Quality and Drug Control Program

Guidelines for Use of Unit-Dose Packaging for the Management and Administration of Pharmaceuticals in Long Term Care Facilities

In accordance with Department of Public Health (Department) regulations at 105 CMR 150.000 *et seq.* and 105 CMR 700.000 *et seq.*, long term care facilities (facilities) may use unit-dose packaging for management and administration of pharmaceuticals in accordance with the following guidelines.

Definition(s)

Unit-dose packaging means an individual drug product container, usually consisting of foil, molded plastic or laminate with indentations into which a single solid oral dosage form is placed, with any accompanying materials or components including labeling. Each individual container is fully identifiable and protects the integrity of the dosage form.

Guidelines

1. Written policies and procedures must be developed and implemented that describe the procurement, administration, storage, security, disposal and record-keeping necessary to assure accountability throughout the system, prevent medication errors, impede drug diversion and facilitate the recall of prescription drug products.
2. Policies must include the manner in which provisions for alternate deliveries will be made in the event of an emergency situation (such as daily delivery not possible), new admissions to the facility or a patient or resident choosing an alternate pharmacy provider.
3. Policies and procedures must comply with all applicable state and federal laws. The Department does not require a waiver or advance approval for use of unit-dose packaging.
4. The policies and procedures must be approved by the facility's administration, nursing and medical staffs.
5. Appropriate training must be provided to the nursing staff as part of orientation and whenever significant system changes are made.
6. The system must be periodically evaluated as part of the facility's quality assurance/continuous quality improvement program.

Additional Information

This policy only covers utilization of unitdose packaging for medication management and administration. There are separate requirements for the implementation of a system of return for redispensing of unit-dose medications.

There are additional requirements that apply to the use of automated dispensing machines in long term care facilities¹.

¹ Department of Public Health, Circular Letter DHCQ 3-98-380.